510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of **21 CFR §807.92.**

APR 16 2010

Submitter Information:

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Date Summary Prepared: 21st February 2010

Contact Person: Christopher Kelly

Device Name:
Trade Name(s): **Airwayease MAS**
Classification Name: **Device, Anti-snoring (21CFR872.5570)**
Panel: **Dental**
Product Code: **LRK**

Predicate Device Information:

Device Name	Manufacturer	510(k) Reference
SomnoMed MAS Flex "S"	SomnoMed Inc	K073004

Device Description:
The Airwayease MAS is an intra-oral device used for treating Snoring and mild to moderate Obstructive Sleep Apnoea. It consists of two custom fitted trays which fit over the upper and lower teeth and engage by means of interchangeable lugs. The device functions as a mandibular repositioner, which acts to increase the patient's pharyngeal space during sleep and improves their ability to exchange air during sleep.

The device is custom made for each patient and has the adjustment mechanism enabling the amount of mandibular advancement as well as vertical change to be set by the dentist or physician at the time of fitting the device.
The ranges of mandibular advancement are up to 7mm from the starting point of the construction bite supplied by the dentist, as well as 7mm of vertical opening from the starting point of the construction bite supplied by the dentist.
Lateral movement of the jaw is limited by the device and as such this device is contra-indicated for those patients requiring the ability to move their lower jaw in a lateral direction whilst wearing the device.
Vertical opening for the Airwayease MAS is unrestricted except by that of the patient's individual physiology.

Intended use - The Airwayease MAS is intended to reduce or alleviate night time snoring and mild to moderate obstructive sleep apnoea.

Target population - Adult patients 18 years or older who have a problem with snoring or obstructive sleep apnoea.

Environment of Use - The device is initially fitted under the supervision of a licensed practitioner (dentist or physician) and is subsequently used in either a home environment or in a sleep laboratory.

Materials – The material composition of the Airwayease MAS is identical to the Ivocap Elastomer cleared in K896130. No colorants or additives have been added to the originally cleared Ivocap Elastomer. NO evidence of biocompatibility issues with previous use of the same material in other dental appliances is known.
The lugs in the Airwayease MAS which are made from DuPont Nylon and is identical to that used in the predicate appliance EMA (K971794), no evidence is known that biocompatibility is an issue.

Comparison to Predicate Device:

The Airwayease MAS is substantially equivalent to the SomnoMed MAS Flex "S" with the soft lining material (SMH Flex "S") for retention. The two types of retention are the same and the Airwayease MAS is entirely made out of- "Ivocap Elastomer" tm which is technologically advanced to grip around the tooth creating a good retention which is designed for patient comfort, this negates the need for metal retention such as ball clasps. The Ivocap Elastomer also allows the interchangeable adjustment components to be removed and exchanged in the event of a desired change in position for the lower jaw. In the event that the components are exchanged they might simply be secured into the base with acrylic, making them secure. This difference does not have significant effect on the safety or effectiveness of the Airwayease MAS.

Comparison Data of Predicate devices				
Attributes	Somnomed MAS flex K0703004	OASYS K030440	TAP III K062951	Airwayease MAS
Indications for use				
Treatment of snoring in Adults	Yes	Yes	Yes	Yes
Treatment of mild to moderate sleep apnoea	Yes	Yes	Yes	Yes
Contra-Indications for use				
Intended to be used with patients who wear full or partial dentures.	NO	NO	NO	NO
intended for lateral bruxers	NO	NO	NO	NO
Use				
Intra Oral device for overnight use	Yes	Yes	Yes	Yes
Single patient multi use	Yes	Yes	Yes	Yes
Use at home or in sleep lab	Yes	Yes	Yes	Yes
Prescription device	Yes	Yes	Yes	Yes
Action				
Works by mandibular advancement and vertical repositioning	NO	NO	NO	Yes
Design				
Custom fit for each patient	Yes	Yes	Yes	Yes
Rigid separate upper and lower tray pieces	Yes	Yes	Yes	No
Flexible separate upper and lower tray pieces	No	No	No	Yes
Can be adjusted or refit	Yes	Yes	Yes	Yes
Lower jaw adjustment using a supplied adjustment key or interchangeable part	Yes	Yes	Yes	Yes
Permits patient to breathe through mouth	Yes	Yes	Yes	Yes
Materials				
Trays constructed from hard acrylic and ball clasps	No	yes	No	No
Trays made from a soft lined self cure material	Yes	No	Yes	No
Trays made from thermo plastic material	No	No	Yes	No

The difference between the intended device Airwayease MAS and the predicate devices are the materials. All of the predicates act as mandibular advancement splints for the treatment of Snoring and mild to moderate Obstructive Sleep Apnoea. This difference does not have significant effect on the safety or effectiveness of the Airwayease MAS.

Justification for the use of the Ivocap Elastomer in the fabrication of the Airwayease MAS is to be able to have a secure well fitting appliance that is able to withstand the destructive forces of the mouth. The material provides comfort in the flexibility of the material when being worn at night and this same flexibility reduces the occurrence of breakages suffered by other rigid materials used in other MAS devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 1 6 2010

Mr. Christopher Kelly
Owner
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Bella Vista, New South Wales
AUSTRALIA 2153

Re: K090436
Trade/Device Name: Airwayease MAS
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea.
Regulatory Class: II
Product Code: LRK
Dated: February 21, 2010
Received: March 30, 2010

Dear Mr. Christopher Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090436

Indications for Use

510(k) Number (if known): K090436

Device Name: Airwayease MAS

Indications for Use:

The Airwayease MAS is intended to reduce or alleviate night time snoring and mild to moderate obstructive sleep apnea (OSA).

Prescription Use ___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Betz DDS for Dr Susan Runner

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K090436